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PATENT

ATTORNEY DOCKET: 59866.000002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number :

09/546,573

Confirmation No.:

3408

Applicant

Mads HOLTEN-ANDERSEN, et al.

Filed

: April 10, 2000

Title

TISSUE INHIBITOR OF MATRIX METALLOPROTEINASES

TYPE-1(TIMP-1) AS A CANCER MARKER

TC/Art Unit

: 1643

Examiner:

: S. L. Rawlings

Docket No.

59866.000002

Customer No.

21967

MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, and in compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, applicants submit attached Form PTO-SB/08A (modified) for consideration and request the references cited therein be made of record by the U.S. Patent and Trademark Office in the above-captioned application.

Applicant wishes to inform the Examiner of the existence of the following copending U.S. patent application:

U.S. Patent Application No. 10/470,658 filed March 28, 2005, entitled "A Method for Detecting, Screening, and /or Monitoring a Cancer in an Individual" (attorney docket number: 59866.00005). A copy of this U.S. Patent Application as filed is enclosed.

Applicants respectfully point out that the submission of the listed references in this Information Disclosure Statement is not an admission that they are prior art or that they are material to patentability of any claims of the application. Also, the submission of this Information Disclosure Statement is not an indication that a search has been made by Applicants.

For the convenience of the Examiner in considering the cited references, a copy of each of the cited references is enclosed with this communication. In considering the cited

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references, it may be noted by the Examiner that certain of the references may contain markings, underlinings, and/or other notations. These markings, underlinings, and/or other notations are not to be construed as drawing the Examiner's attention either to selected parts or away from other parts of the cited references. Any such markings were either present on the copies of the cited references obtained by the associated individuals, or were made thereon during the study of the references by the associated individuals.

Consideration of the foregoing plus the prompt return of a copy of the enclosed Form SB/08A with the Examiner's initials in the left column in accordance with MPEP 609 are respectfully requested.

In accordance with 37 C.F.R. § 1.97(b), this Information Disclosure Statement is believed to be submitted prior to issuance of a first Office Action on the merits, or a Notice of Allowance. Therefore, it is respectfully submitted that no fee is required for consideration of this information. However, in the event any fee is deemed necessary, the Commissioner is authorized to charge the undersigned's Deposit Account No. 50-0206.

Bv:

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: February 1, 2006

Stanislaus Aksn

Registration No. 28,562

Hunton & Williams LLP Intellectual Property Department 1900 K Street, N.W. Suite 1200 Washington, DC 20006 (202) 955-1500 (telephone) (202) 778-2201 (facsimile) SA/asc

Mads HOLTEN-ANDERSEN, et al.

PTO/SB/08B (08/03) (modified) U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

09/546,573

April 10, 2000

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

FEB 0 1 2006

Art Unit 1643 (use as many sheets as necessary) Examiner Name S. L. Rawlings

Application Number

First Named Inventor

Filing Date

Sheet 1 of 3 Attorney Docket Number 59866.000002

*Examiner Initials	Cite No.	DOCUMENT NUMBER Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US- 10/470,658	03-28-2005	Lasse L. HESSEL, et al.	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PTO/SB/08B (08/03) (modified) U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Substitute for form 1449/PTO Application Number 09/546.573 Filing Date April 10, 2000 INFORMATION DISCLOSURE Mads HOLTEN-ANDERSEN, et STATEMENT BY APPLICANT First Named Inventor (use as many sheets as necessary) Art Unit 1643 Examiner Name S. L. Rawlings Sheet 2 of 3 Attorney Docket Number 59866.000002 OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the TRANSLATION *Examiner item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue Initiate No. number(s), publisher, city and/or country where published NO 2. Agency for Health Care Policy and Research, "Colorectal Cancer Screening: Summary", Evidence Report: Number 1. AHCPR Publ. No. 97-0302, pg. 1-4. 3. Aznavoorian S. et al., "Molecular Aspects of Tumor Cell Invasion and Metastasis", Cancer, 15, 71(4), pg. 1368-1383, 1993. 4. Balk, S. P. et al., "Biology of Neoplasia, Biology of Prostate-Specific Antigen", Journal of П Clinical Oncology, 21 (2), pg. 383-391, 2003. 5. Benson, A. B., et al., "ASCO Special Article - 2000 Update of American Society Colorectal Cancer Surveillance Guidelines", Journal of Clinical Oncology, 18(20), pg. 3586-3588, October 15, 2000. 6. Birkedal-Hansen, "Role of Matrix Metlloproteinases in Human Periodontal Diseases", J. Periodontal., pg. 474-484, May 1993. 7. Breimer, D. D., et al., "Saliva: A Fluid for Measuring Drug Concentrations", Pharmacy П Internation, 1, pg. 9-11, 1980. 8. Khokha, R. et al., "AntisenseRNA-Induced Reduction in Murine TIMP Levels Confers Oncogenicity on Swiss 3T3 Cells", Science, 243, pg. 947-950, February 17, 1989. 9. Kleiner, et al., "Stability Analysis of Latent and Active 72-kDa Type IV Collagenase: The Role of Tissue Inhibitor of Metalloproteinases-2 (TIMP-2)", Biochemistry, 32, pg. 1583-1592, 1993. 10. Lovgren, J., et al., "Measurement of Prostate-Specific Antigen and Human Glandular Kallikrein 2 in Different Body Fluids", J. Andrology, 20, pg. 348-355, 1999. Remacle, A. et al., "High Levels of TIMP-2 Correlate with Adverse Prognosis in Breast 11. Cancer", Int. J. Cancer, 89, pp: 118-121, 2000. 12. Stetler-Stevenson WG et al., "Matrix Metalloproteinases and Tumor Invasion: From Correlation and Causality to the Clinic", Semin. Cancer. Biol., 7, pp. 147-154, 1996.

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

DATE CONSIDERED

EXAMINER SIGNATURE

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Application Number	09/546,573 April 10, 2000 Mads HOLTEN-ANDERSEN, et al. 1643		
Filing Date			
First Named Inventor			
Art Unit			
Examiner Name	S. L. Rawlings		
Attorney Docket Number	59866.000002		

Sheet		3 of 3	Attorney Docket Number	59866.000002	-	
		OTHER DOCUMENTS - NON	I-PATENT LITERATURE	DOCUMENTS		
*Examiner	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue			TRANSLATION	
- 100 March 1990	1	number(s), publisher, city and/or country where published				
13.		Turan T. et al., "Free and Total Prostate-Specific Antigen Levels in Saliva and the Comparison with Serum Levels in Men", Eur. Urol., 38(5), pp. 550-554, 2000. Vignola et al., "Sputum Metalloproteinase-9/Tissue Inhibitor of Metalloproteinase-1 Ratio Correlates with Airflow Obstruction in Asthma and Chronic Bronchitis", Am. J. Respir. Crit. Care Med., 158, pp. 1945-1950, 1998.				
16		Welgus HG et al., "Human Skin Fibroblast Collagenase Interaction with Substrate and Inhibitor", Coll. Relat. Res., 5, pp. 167-179, 1985.				
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	18.	Garrett, C. Durkan et al., "Prognostic Significance of Matrix Metalloproteinase-1 and Tissue Inhibitor of Metalloproteinase-1 in Voided Urine Samples from Patients with Transitional Cell Carcinoma of the Bladder", Clin. Cancer Res., 7, pp. 3450-3456, Nov. 2001.				
	19.	Birkedal-Hansen, H. et al., "Matrix Metalloproteinases: A Review", Crit. Rev. Oral. Biol. Med., 4(2), pp 197-250, 1993.				
	20.	McCarthy K. et al., "High Levels of Tissue Inhibitor of Metalloproteinase-1 Predict Poor Outcome in Patients with Breast Cancer", Int. J. Cancer, 84, pp. 44-48, 1999.				
EXAMINER SIGNATURE DATE CONSIDERED						

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